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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/552,994	04/21/00	MONTGOMERY	R 13045

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EXAMINER

ART UNIT	PAPER NUMBER
1711	5

DATE MAILED:

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/552,994

Applicant(s)

Montgomery et al.

Examiner

Jeffrey Mullis

Group Art Unit
1711



☒ Responsive to communication(s) filed on Nov 15, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire three month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-56 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-56 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Claims 7, 43 and 52-55 contains the trademark/trade name "MLU"-340 etc.

Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. § 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade name is used to identify/describe a non-descript indefinite dimethacrylate oligomer and, accordingly, the identification/description is indefinite.

Claims 7-9, 19-21 and 32-55 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention.

The term "MLU"-340 etc. is not art recognized and is therefore unclear.

The term "molecular weight" is not clear where this term is unqualified as to the type of molecular weight, i.e. for instance

number or weight average molecular weight since weight average or number average, etc. since molecular weights may differ greatly depending on the type of molecular weight.

The term "bioadhesion synergist" is not art recognized and is therefore unclear.

It is not clear what is being claimed in claim 32 since claim 32 recites a "two part composition". Since a composition is a mixture of materials, it is unclear how mixture can be in different parts, i.e. aside from a mixture. If applicants actually are claiming a mixture of all the materials recited in claim 32 it is not clear what "two part" refers to.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. ~~Patentability shall not be negatived by the manner in which~~ the invention was made.

Claims 1-51 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Jensen et al. (USP 6,086,370) in view of Yamamoto et al. (USP 5,530,038), Della Valle et al. (USP 5,876,744) and Peppas et al., Biomaterials 17 (1996) pages

1553-1561, cited by applicants and Kanerva et al., Contact Dermatitis, 33, pages 84-89 (1995).

Jensen et al. disclose a composition for adhering two substrates (Abstract) containing "polymerization strength reducers" intended to reduce the amount of heat that the patient experiences, said materials including polyethylene glycols and other diluents (note column 7 line 55 - column 8 line 33) and also containing tissue adherence accentuators such as polyethylene oxides, xanthan gum or guar gum (note the paragraph bridging columns 8 and 9) and also containing materials such as titanium dioxide and silicon dioxide such as in applicants' "light attenuating pigment" (note column 9 lines 14-45). Note the use of photoinitiators such as camphorquinone and curing assistants such as dimethyl toluidine at column 7 lines 30-42.

The primary reference Jensen et al. does not disclose that his composition may be in the form of a "two part composition" as in instant claim 32, does not disclose that the curing agent synergist is ethyl-4-dimethylaminobenzoate, does not disclose

that the a bioadhesion synergist may be added and does not disclose urethane dimethacrylates as in instant claim 43.

Yamamoto et al. disclose an adhesive composition which may beneficially contain a combination of camphorquinone and diethylaminobenzoic acid when room temperature curing is desired at column 6 lines 20-57 and which may be in the form of a two

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part kit at column 10 lines 1-9 in order that the material be more effectively stored.

Della Valle et al. disclose a composition having high bioadhesion and which includes polyethylene glycols and Polycarbophil at column 2 lines 37-43 and which has higher bioadhesive properties than Polycarbophil at column 3 lines 5-10 (although the material contains Polycarbophil). This is despite the fact that Polycarbophil by itself is disclosed as having higher adhesive properties than other adhesive materials alone at column 2 lines 48-56.

Kanerva et al. discloses that urethane dimethacrylates have very low irritative effects. Note Table 4 in this regard.

Cordes et al. (USP 6,153,216) and Kumar et al. (USP 5,006,571) both disclose that divalent salts such as calcium or trivalent salts may be added to adhesive formulations. Note in this regard Kumar et al. discloses that carboxyl containing materials and adhesives may have their adhesiveness increased by addition of such salts at the paragraph bridging columns 3 and 4.

Note column 4 lines 33-37 of Cordes et al. for similar teaching.

It would have been obvious to a practitioner having ordinary skill in the art at the time of the invention to use camphorquinone and ethyldimethylaminobenzoate as taught by Yamamoto since Yamamoto et al. disclose that such curing agent and synergist combination may be used at room temperatures and

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since the primary reference discloses an adhesion which requires curing at room temperature and absent any showing of surprising or unexpected results.

It would have been obvious to a practitioner having ordinary skill in the art at the time of the invention to form the composition of Jensen et al. into a two part kit combination in order to facilitate storeability as taught by Yamamoto et al. and absent any showing of surprising or unexpected results.

It would have been obvious to a practitioner having ordinary skill in the art at the time of the invention to use urethane dimethacrylates as taught by Peppas et al. since Peppas et al. disclose that such materials have very low irritative effects absent any showing of surprising or unexpected results.

It would have been obvious to a practitioner having ordinary skill in the art at the time of the invention to use Polycarbophil as the adhesion promoter in the composition of the primary reference since Della Valle et al. specifically disclose that Polycarbophil containing compositions can exhibit unusually high adhesive properties and absent any showing of surprising or unexpected results.

It would have been obvious to a practitioner having ordinary skill in the art at the time of the invention to add divalent or trivalent adhesion synergists to the composition of Jensen et al.

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as taught by Kumar and Cordes in order to increase adhesiveness absent any showing of surprising or unexpected results.

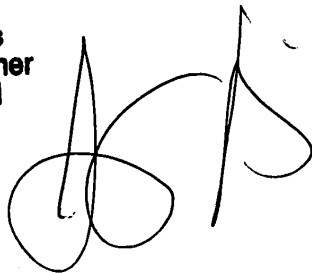
Although there is no teaching regarding applicants' peak exotherm characteristic, the primary reference specifically discloses that the composition which is in contact with human tissue did not cause discomfort due to heating; therefore minimization of the temperature of curing and amount of heat (such as would result in minimization of peak exotherm characteristic) would have been obvious to a practitioner having ordinary skill in the art at the time of the invention based on the teachings of the primary reference in order to minimize discomfort to the patient absent any showing of surprising or unexpected results.

Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 119(e) as follows:

An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification (37 CFR 1.78).

Any inquiry concerning this communication should be directed to Jeffrey Mullis at telephone number (703) 308-2820.

Jeffrey Mullis
Primary Examiner
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A handwritten signature in black ink, consisting of a large, stylized 'J' and 'M' intertwined.